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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

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12/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,557	NASH ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-10,42 and 45-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-10,42 and 45-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment entered October 3, 2007 has been entered. Claims1, 5, 7, 9, 10, 42 and 48 have been amended. Claims 2-4, 6, 11-41 and 43-44 have been cancelled. Claims 1, 5-10, 42 and 45-48 are under consideration in this office action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in vie of applicants' amendments and arguments:

a) The written description rejection of claims 1-2, 5-13 and 42-48 under 35 U.S.C. 112, first paragraph;

b) The rejection of claims 1, 2, and 5-13 under 35 U.S.C. 112, second paragraph;

c) The rejection of claims 1-2, 5-7, 11, 42-43 and 45 under 35 U.S.C. 102(b) as being anticipated by Tokoro (US Patent 5,080,895);

d) The rejection of claims 1-2, 5-7, 11-12 and 42-45 under 35 U.S.C. 102(b) as being anticipated by Stolle et al., (US Patent 4,748,018); and

e) The rejection of claims 8-10 and 47-48 under 35 U.S.C. 103(a) as being unpatentable over Tokoro (US Patent 5,080,895) and Coleman (US Patent 5,585,098) further in view of Ishihara et al., (US Patent 6,068,862).

Response to Arguments

3. Applicant's arguments with respect to claims 1, 5-10, 42 and 45-48 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection Necessitated By Amendments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 5-10, 42 and 45-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for a microbial adherence inhibitor or method of producing the inhibitor for administration to animals to inhibit the adherence of targeted colony-forming immunogens with respiratory viruses comprising swine influenzae (H1N1, H3N2) in the respiratory tracts of said animals produced by the method of: A. Inoculating female birds, in or about to reach their egg laying age, with a targeted colony-forming immunogen of respiratory viruses comprising swine influenzae (H1N1, H3N2); B. Allowing a period of time sufficient to permit the production in the bird of antibody-containing

contents in the bird's eggs to the targeted colony-forming immunogen of respiratory viruses comprising swine influenzae (H1N1, H3N2), said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs; C. Harvesting the eggs laid by the birds; D. Separating the antibody-containing contents of said eggs from the shells thereby creating the microbial adherence inhibitor that binds to colony-forming illness –causing immunogens in the respiratory tracts of animals.

Applicant did not point to support in the specification for a microbial adherence inhibitor or method of producing the inhibitor for administration to animals to inhibit the adherence of targeted colony-forming immunogens with respiratory viruses comprising swine influenzae (H1N1, H3N2) in the respiratory tracts of said animals produced by the method. Moreover, applicant failed to specifically point to the identity or provide structural characteristics of a microbial adherence inhibitor that inhibits the adherence of the immunogens. Thus, there appears to be no teaching of a microbial adherence inhibitor that inhibits the adherence of the immunogens. Applicant has not pointed to any pages of the instant specification and claims for support of the amendment drawn to the microbial adherence inhibitor that inhibits the adherence of the immunogens. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity of a microbial adherence inhibitor that inhibits the adherence of the immunogens as recited by the amendments. Therefore, the claims incorporate new matter and are accordingly rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 5, 7-9, 42 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US Patent 5,367,054) in view of Okuno et al., (US Patent 6,337,070).

Claim 1 is drawn to a microbial adherence inhibitor for administration to animals to inhibit the adherence of targeted colony-forming immunogens with respiratory viruses comprising swine influenzae (H1N1, H3N2) in the respiratory tracts of said animals produced by the method of: A. Inoculating female birds, in or about to reach their egg laying age, with a targeted colony-forming immunogen of respiratory viruses comprising swine influenzae (H1N1, H3N2); B. Allowing a period of time sufficient to permit the production in the bird of antibody-containing contents in the bird's eggs to the targeted colony-forming immunogen of respiratory viruses comprising swine influenzae (H1N1, H3N2), said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs; C. Harvesting the eggs laid by the birds; D. Separating the antibody-containing contents of said eggs from the shells thereby creating the microbial adherence inhibitor that binds to colony-forming illness –causing immunogens in the respiratory tracts of animals. Claim 5 is drawn to the antibody containing contents obtained from specific egg-laying animals; and claim 7 is drawn to the mixing the separated contents with a carrier material. Claim 42 is drawn to a

method of producing a microbial adherence inhibitor for administration to animals to inhibit the adherence of targeted colony-forming immunogens in the respiratory tracts of said animals produced by the method of: A. Inoculating female birds, in or about to reach their egg laying age, with a targeted colony-forming immunogen of respiratory viruses comprising swine influenzae (H1N1, H3N2); B. Allowing a period of time sufficient to permit the production in the bird of antibody-containing contents in the bird's eggs to the targeted colony-forming immunogen of respiratory viruses comprising swine influenzae (H1N1, H3N2), said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs; C. Harvesting the eggs laid by the birds; D. Separating the antibody-containing contents of said eggs from the shells thereby creating the microbial adherence inhibitor that binds to colony-forming illness –causing immunogens in the respiratory tracts of animals. Claim 45 is drawn to the mixing the separated contents with a carrier material.

Lee teaches the eggs are produced by bringing the subjects to a state of hyperimmunization by means of primary immunization with specific antigens, such as viral antigens (col. 7, lines 50-56). Lee teaches the egg produced by the animals in the hyperimmune state and immune eggs (col.7, lines 60-63). Lee teaches taking eggs from a hyperimmune avian animal (col. 7, lines 48-50). Lee teaches using avian animals including poultry, chickens, turkeys, geese, ducks and caged birds (col. 4, lines 2-4). Lee teaches using the purified egg yolk immunoglobulins, mainly IgY, IgA and IgM from immune egg yolk (col. 3, lines 35-37). Lee teaches a variety of means of separation wherein the eggs are collected, cracked and the egg is then subjected to purification (see example1). Lee teaches that the product is useful for pharmaceutical purposes such as immunization (col. 3, lines 38-40). Lee et al., teach drying the

protein fraction from a de-salted fraction, thereby mixing the antibody contents with a dry carrier material (example12). However, Lee does not teach inoculating the birds with respiratory viruses comprising swine influenzae (H1N1, H3N2).

Okuno et al., teach inoculation with respiratory viruses comprising swine influenzae (H1N1, H3N2). Okuno et al., teach that influenzae viruses H1N1 and H3N2 subtypes of the virus (col1, lines 25-30). Okuno et al., teach the need for antibodies takes having cross-recognizing ability for influenzae virus A virus subparticles and has a virus neutralization activity (col.2, lines 22-25). It is well known in the art that people get sick from avian-human influenzae viruses generated in pigs because pigs have vectors for both avian and human receptors, thus there is a need prevent interspecies transmission. Okuno et al., teaches the need for a safe vaccine (col.2, lines 20-22).

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention incorporate inoculation with respiratory viruses comprising swine influenzae (H1N1, H3N2) as taught by Okuno et al., to the microbial adherence inhibitor and method of Lee in order to have antibody containing contents that have cross-recognizing ability for influenzae virus A virus subparticles. One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Lee teach the desire to produce IgY, IgA and IgM antibody containing products using for pharmaceutical applications for the treatment of other animals. Furthermore, one having ordinary skill in the art would have been motivated to do this because Lee and Okuno et al., teach primary immunization with specific antigens, such as viral antigens. Finally it would have been prima facie obvious to

combine the invention of Lee and Okuno et al., to advantageously achieve virus neutralization activity and protection against infectious viral illness in animals.

6. Claims 1, 5, 7-9, 42 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tokoro (US Patent 5,080,895) in view of Okuno et al., (US Patent 6,337,070).

Claim 1 is drawn to a microbial adherence inhibitor for administration to animals to substantially prevent the adherence of targeted colony-forming immunogens with respiratory viruses comprising swine influenzae (H1N1, H3N2) in the respiratory tracts of said animals produced by the method of: A. Inoculating female birds, in or about to reach their egg laying age, with a targeted colony-forming immunogen of respiratory viruses comprising swine influenzae (H1N1, H3N2); B. Allowing a period of time sufficient to permit the production in the bird of antibody-containing contents in the bird's eggs to the targeted colony-forming immunogen of respiratory viruses comprising swine influenzae (H1N1, H3N2), said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs; C. Harvesting the eggs laid by the birds; D. Separating the antibody-containing contents of said eggs from the shells thereby creating the microbial adherence inhibitor that binds to colony-forming illness –causing immunogens in the respiratory tracts of animals. Claim 5 is drawn to the antibody containing contents obtained from specific egg-laying animals; and claim 7 is drawn to the mixing the separated contents with a carrier material. Claim 42 is drawn to a method of producing a microbial adherence inhibitor for administration to animals to substantially prevent the adherence of targeted colony-forming immunogens in the respiratory tracts of said animals produced by the method of: A. Inoculating female birds, in or

about to reach their egg laying age, with a targeted colony-forming immunogen of respiratory viruses comprising swine influenzae (H1N1, H3N2); B. Allowing a period of time sufficient to permit the production in the bird of antibody-containing contents in the bird's eggs to the targeted colony-forming immunogen of respiratory viruses comprising swine influenzae (H1N1, H3N2), said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs; C. Harvesting the eggs laid by the birds; D. Separating the antibody-containing contents of said eggs from the shells thereby creating the microbial adherence inhibitor that binds to colony-forming illness –causing immunogens in the respiratory tracts of animals. Claim 45 is drawn to the mixing the separated contents with a carrier material.

Tokoro teaches a method of producing a microbial adherence inhibitor and the microbial adherence inhibitor for administration to animals to substantially prevent the adherence of targeted colony-forming immunogens in the respiratory tracts of said animals produced by the method of: A. Inoculating hens, in their egg laying age, with a targeted colony-forming immunogen (col. 5, lines 29-31); B. Allowing a period of time sufficient to permit the production in the bird of antibody-containing contents in the bird's eggs to the targeted colony-forming immunogen (col. 5, lines 47-52); C. Harvesting the eggs laid by the birds (col. 5-6, lines 67-1); D. Separating the antibody-containing contents of said eggs from the shells (col.6, lines 8-12). The antigens used to immunize hens include pollens, bacteria, viruses, molds, allergens, or a combination of antigens (col. 4, lines 50-57). The reference microbial adherence inhibitor such as dried egg antibody is used as an additive to food for animal to prevent adherence of the targeted immunogen (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging

column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). Tokoro teaches the yolk being separated from the egg since the yolk contains most of the antibodies (col. 6, lines 10-12).). However, Tokoro does not teach inoculating the birds with respiratory viruses comprising swine influenzae (H1N1, H3N2).

Okuno has been discussed above as teaching inoculation with respiratory viruses comprising swine influenzae (H1N1, H3N2).

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention incorporate inoculation with respiratory viruses comprising swine influenzae (H1N1, H3N2) as taught by Okuno et al., to the microbial adherence inhibitor and method of Tokoro in order to have antibody containing contents that have cross-recognizing ability for influenzae virus A virus subparticles. One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Tokoro teach using viral immunognes, as the targeted colony forming immunogens, along with the desire to produce antibody containing products useful for the treatment of other animals. Furthermore, one having ordinary skill in the art would have been motivated to do this because Tokoro teach primary immunization with specific antigens, such as viral antigens. Finally it would have been prima facie obvious to combine the invention of Tokoro and Okuno et al., to advantageously achieve virus neutralization activity and protection against infectious viral illness in animals.

7. Claims 8-10 and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US Patent 5,367,054), Okuno et al., (6,332,070) and Coleman (US Patent 5,585,098) further in view of Ishihara et al., (US Patent 6,068,862).

Claims 8 and 46 are drawn to a mixing and pasteurization step; and claims 9 and 47 are drawn to a storage step. Claims 10 and 48 are drawn to the material of the carrier material being distilled dried grains or dried beet pulp.

Lee and Okuno et al., have been discussed above, however neither teach: a mixing and pasteurization step; storage steps or the carrier material being distilled dried grains.

Coleman teach mixing the separated antibody containing contents and pasteurizing those contents (col. 6, lines 1-3). The chicken antibody is not harmed by pasteurization (col. 6, lines 2-3). Pasteurization is the process of heating for the purpose of destroying viruses and harmful organisms such as bacteria, protozoa, molds and yeasts. Coleman et al., teach the administration of chicken antibodies obtained from the egg of a hen immunized against a pathogenic organisms to thereby elicit antibodies and administer those antibodies to cows (abstract). Extraction of yolk antibodies is performed even on a large scale without costly investment (col. 5, lines 65-68). Concentrating the antibody from egg yolk is a relatively straightforward process (col. 5-6, lines 68-1). Thus, there would be no problem with consumption of milk from dairy cattle treated with egg yolk antibodies, and no mandatory milk-withholding period, in sharp contrast to antibiotics (col. 6, lines 5-9). Thus the antibody contents and carrier material are stored in milk cartoon, thereby teaching a storage step.

Ishihara et al., teach dried grains as carrier material which is mixed with the microbial adherence inhibitor antibody (col. 5, lines 30-35, and Examples 9 and 10).). Ishihara et al., teach

feed for poultry including grains such as corn feed, and wheat bran; while feed for dairy cows contains grains such as corn, rye and wheat bran (Examples 9 and 10). The animal feed additive is a specific antibody that specifically binds to an infectious microorganism or virus is produced from chicken egg antibodies obtained from eggs of egg laying hens hyperimmunized with infectious microorganisms or viruses (col. 5, lines 30-35). The animal feed additive and the animal feed containing the additive are useful in preventing and treating illness associated with rapid environmental changes, feed composition changes and inappropriate breeding husbandry or infectious diarrhea induced by viruses, improves intestinal functions, feed efficiency and eliminates fecal and urinary malodor (col. 4, lines 9-20).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to mix animal feed such as grains as taught by Ishihara et al., with Lee, Okuno et al., and Coleman in order to prevent and treat illness in farm animals as taught by Lee, Okuno and Coleman. One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Lee, Coleman and Ishihara et al., teach treating animals with microbial adherence inhibitors as a means of immunizing animals against pathogens. One having ordinary skill in the art would have been motivated to do this because the Ishihara et al., teach the animal feed additives being mixed with carrier the materials of animal feed improves intestinal functions, feed efficiency and eliminates malodor. Finally it would have been prima facie obvious to combine the invention of Lee, Okuno, Coleman and Ishihara et al., to advantageously achieve protection against infectious viral illness in domestic animals.

Conclusion

8. No claims allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
December 19, 2007

MARK NAVARRO
PRIMARY EXAMINER